

**REMARKS**

The Office Action dated November 21, 2003 presents the examination of claims 1-8. Withdrawn claims 10-25 are canceled herein. Claim 29 is added. Support for claim 29 is found on page 7, line 26 of the specification. Claims 1, 3, 8, and 26 are amended. Support for "32 to 42°C" added to claims 1 and 26 is found on page 8, line 5 of the specification. Support for step "(f)" in claim 1 is found on page 6, lines 11-15. Upon entry of this Reply, claims 1-8 and 26-29 will be pending. No new matter is inserted into the application.

***Claims 26-28***

Claims 26-28 were added in the Reply under 37 C.F.R. § 1.111 filed on August 20, 2003. The Office Action makes no mention of these claims. The Examiner is respectfully requested to enter claims 26-28 into the record.

***Request for Initialed Form PTO-1449***

An Information Disclosure Statement was filed in connection with the present application on May 24, 2001. The Examiner is respectfully requested to consider the IDS and the references cited therein, and to initial and return the form PTO-1449 filed therewith. A copy of the form PTO-1449 is attached hereto for the Examiner's convenience.

***Claim Objections***

The Examiner objects to claims 1 and 8 for minor informalities. In order to overcome the objection to the claims, Applicants amend claims 1 and 8 as suggested by the Examiner. Withdrawal of the instant objection is therefore respectfully requested.

***Drawings Pursuant to the Examiner's Request***

Attached hereto are copies of drawings 1-6 in response to the Examiner's request.

***Rejection under 35 U.S.C. § 112, second paragraph***

The Examiner maintains the rejection of claims 1-8 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

***Claim 1***

Specifically, the Examiner maintains that the referral to "the Typing Table" in claim 1 is unclear. In particular, the Examiner asserts that it is unclear from where the typing table originates. The typing table is not already "known," but rather is generated by a skilled artisan during the method of claim 1. Claim 1 is amended to add a step wherein a typing table is

generated. Support to step "(f)" in claim 1 is found on page 6, lines 11-15. As noted in the specification, a person skilled in the art can easily generate the Typing Table.

Claim 3

The Examiner states that the recitation of "which specifically bonds to..." in claim 3 is unclear. Claim 3 is amended to recite "binds" instead of "bonds." This amendment is made merely to correct the idiomatic nature of the claim language and does not add new matter.

Applicants respectfully submit that the instant claims particularly point out and distinctly claim the subject matter that is the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

***Rejection under 35 U.S.C. § 103(a)***

Claims 1-4 and 8

The Examiner rejects claims 1-4 and 8 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Kawai et al. (*Human Immunology*, 41:121-126 (1994)), in view of GenBank Accession Number X97645 (December 2, 1996), in view of Tokunaga et al. (*Human Immunology*, 47:103 (1996)), and further in view of Olejnik et al. (*Nucleic Acids Research*, 26:3572-3576(1998)). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Kawai et al. teaches microtiter plate hybridization. GenBank Accession Number X97645 contains SEQ ID NO:3 at positions 79-97. Tokunaga et al. teaches using microtiter plate hybridization for typing HLA alleles. Olejnik et al. describes amino modifying probes for use as a marker or tag. None of the cited references teach a method wherein a typing table is generated based upon signal patterns.

In the outstanding Office Action, the Examiner asserts that the above is not persuasive since the claims do not require that a typing table be generated based upon signal patterns. In response to the Examiner's remarks, claim 1 is amended to recite that a typing table is generated using signal patterns obtained by hybridizing the PCR amplified products from samples whose HLA class I antigen types or allele types are known with DNA probes which can specifically hybridize with the sequence of at least one specific HLA class I allele. Support to step "(f)" in claim 1 is found on page 6, lines 11-15 of the specification. As noted in the specification, a person skilled in the art can easily generate the Typing Table. None of the cited prior art references disclose or suggest this feature of the present invention.

For all of the above reasons, Applicants respectfully submit that the pending claims are patentable over Kawai et al., in view of GenBank Accession Number X97645, in view of Tokunaga et al., and further in view of Olejnik et al. Withdrawal of the instant

rejection is therefore respectfully requested.

Claims 5-7

The Examiner also rejects claims 5-7 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Kawai et al., in view of GenBank Accession Number X97645, in view of Tokunaga et al., further in view of Olejnik et al., and further in view of Kox et al. (*Journal of Clinical Microbiology*, 34:2117-2120(1996)).

The Examiner relies on Kox et al. to teach a microwell hybridization assay that includes a hybridization reaction in the presence of formamide at 37°C.

Applicants respectfully submit that the Examiner misconstrues the disclosure of Kox et al. In actuality, Kox et al. performs hybridization between the DNA probes and PCR products at room temperature in the presence of 50% formamide. See, page 2118, column 1, line 39 of Kox et al. Thus, contrary to the Examiner's understanding, Kox et al. fails to disclose hybridization between amplified products and immobilized DNA probes at a reaction temperature of 32-42°C.

In contrast, hybridization of the amplified products with the immobilized DNA probes in the present invention occurs at a reaction temperature of 32-42°C. This feature of the present invention is recited in amended claims 1 and 26. Further, as recited in claim 29, hybridization may also be performed in the presence of 5-30% formamide.

Thus, the combination of Kox et al. with Kawai et al., GenBank Accession Number X97645, Tokunaga et al., and Olejnik et al. still fails to teach or suggest each and every claimed element of the present invention.

Further, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 executed by Dr. Toyoki MORIBE (an inventor of the present application) showing that the skilled artisan would not be motivated to combine Kox et al. with the other cited references because use of the reaction temperatures and conditions of Kox et al. would not achieve the present invention.

The first experiment compares the hybridization temperature of Kox et al. with that used in the present invention (and claimed in claims 1 and 26), while the second experiment compares the concentration of formamide utilized by Kox et al. with that of the present invention (and claimed in claim 29). The results of the experiments show that the present invention could not be performed at room temperature (as utilized by Kox et al.) or in the presence of 40% formamide (which is even less than the amount utilized by Kox et al.) because positive and negative signals could not be distinguished under these conditions.

Thus, the Declaration unequivocally shows that hybridization under the conditions disclosed in Kox et al. cannot be used in the present invention. Therefore, the skilled artisan would have no motivation to combine Kox et al. with Kawai et al., GenBank Accession Number X97645, Tokunaga et al., and Olejnik et

al., and further the combination thereof still fails to achieve the present invention.

In summary, Kox et al., Kawai et al., GenBank Accession Number X97645, Tokunaga et al., and Olejnik et al. fail to suggest the present invention under 35 U.S.C. § 103. Withdrawal of the instant rejection is therefore respectfully requested.

### **Conclusion**

Applicants respectfully submit that the above amendments and/or remarks fully address and overcome the rejections of record, such that the present application is in condition for allowance. The Examiner is respectfully requested to issue a Notice of Allowance indicating that claims 1-8 and 26-29 are allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional

Appl. No. 09/856,662

fees required under 37 C.F.R. §§1.16 or 1.17; particularly,  
extension of time fees.

Respectfully submitted,

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Attachments: Declaration under 37 C.F.R. § 1.132  
Copy of PTO-1449  
Copy of Original Drawings